**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| KING PHARMACEUTICALS, INC.; KING PHARMACEUTICALS RESEARCH AND DEVELOPMENT, INC., | ) | |
| Plaintiffs, | ) | |
| v. | ) | Civil Action No. 10-1878 (GEB-DEA) |
| COREPHARMA, LLC, | ) | **MEMORANDUM OPINION** |
| Defendant. | ) | |

**BROWN, Chief Judge**

This matter comes before the Court on April 13, 2010 upon the application for a emergency relief pursuant to FED. R. CIV. P. 65 and L. CIV. R. 65.1 by Plaintiffs King Pharmaceuticals, Inc.; King Pharmaceuticals Research and Development, Inc. (collectively "King"), seeking a preliminary injunction against Defendant Corepharma, LLC ("Corepharma"), enjoining Corepharma from engaging in the use, offer to sell, or sale within the United States of, or importing into the United States, its generic metaxalone product pending a resolution on the merits of the action.

## I. BACKGROUND

This contract case began on April 13, 2010 when King filed a complaint alleging that Corepharma breached an agreement (hereinafter "the Contract") between the two companies by

selling a generic version of metaxalone. (Compl. at ¶ 2; Doc. No. 1.) On March 30, 2010, another generic drug company, Sandoz, received FDA approval to market their generic metaxalone product and attempted an at-risk launch. The Court entered a temporary restraining order ("TRO") in that case on April 1, 2010 to preserve the status quo. On April 6, 2010, the TRO was modified to allow Sandoz to manufacture its generic metaxalone. The modification also contained a self-destruct clause, wherein the TRO would immediately dissolve if Corepharma, King's authorized generic manufacturer, launched a generic metaxalone into the marketplace. On April 9, 2010, this event occurred and the TRO in the Sandoz matter dissolved. This immediately gave Sandoz the right enter the metaxalone market. King then filed this lawsuit, alleging that the terms of their contract with Corepharma did not give Corepharma the right to launch their generic metaxalone product and that King is being irreparably harmed by the presence of both Corepharma's generic metaxalone and Sandoz's generic metaxalone on the market.

The Court entered the application for an order to show cause, but denied to include temporary restraints. There are currently three metaxalone products on the market: (1) King's patented version, known under the trade name Skelaxin; (2) Sandoz's generic; and (3) Corepharma's authorized generic.

## II. DISCUSSION

### A. Standard of Review

A preliminary injunction is a drastic and extraordinary remedy that is not to be routinely granted. *Frank's GMC Truck Center, Inc. v. General Motors Corp.*, 847 F.2d 100, 102 (3d Cir. 1988). In order to obtain the extraordinary relief of a prelminary injunction, plaintiffs must

establish: (1) that they are likely to succeed on the merits, (2) that they are likely to suffer irreparable harm in the absence of preliminary relief; (3) that the balance of equities tips in their favor, and (4) that an injunction is in the public interest. *See, Constructors Ass'n of Western Pennsylvania v. Kreps*, 573 F.2d 811, 814-815 (3d Cir. 1978).

*1. Likelihood of Success on the Merits*

New York law applies to this agreement. (Contract at Section 11.8) Under New York law, King must prove the following elements to succeed on a breach of contract claim: (1) existence of a contract; (2) its performance under the contract; (3) CorePharma's breach of that contract; and (4) resulting damages. *J.P. Morgan Chase v. J.H. Electric of New York, Inc.*, 893 N.Y.S.2d 237 (2d Dept. 2010). The only element in dispute is whether the Contract was breached.

The Contract provides that Corepharma may launch their generic product upon an "At-Risk Launch" by a third party. This happened when Sandoz attempted an at-risk launch on April 1, 2010. However, later that day this Court enjoined Sandoz from launching. King argues that this TRO stopping Sandoz from marketing also meant that Corepharma should stop marketing pursuant to the Contract. Corepharma, on the other hand, argues that once Sandoz attempted an at-risk launch, however brief, Corepharma's right to launch was immediately and irreversably triggered.

The main point of contention between the parties is whether Corepharma was given a right to launch under subsection (c) or subsection (d) of the Authorized Launch Date provision. The relevant portion of the contract provides that:

[Contract provided to the Court under seal]

[redacted]

King argues that, even though an At-Risk launch occurred, subsection (c) is inapplicable because the condition requiring King to verify the At-Risk launch in writing was not met. Subsection (c), as amended, applies to this agreement. Under this provision, the six month waiting period for Core to launch is triggered when King verifies that a first generic sale took place. Subsection (c) also provides that it shall become *effective immediately* if such *first sale* is an at Risk Launch. (*Id.*) (emphasis in original). However, whether Sandoz's actions were an "at-risk launch" as defined in the contract is a serious question not addressed in any of the briefs.

The contract defines "At Risk Launch" as the "marketing, distribution or sale by any Third Party of a generic version of the Branded Product that is not authorized or licensed by King and that follows . . . the expiration of the 30 month stay." (Article I). Sandoz's exact actions between their decision to launch and the TRO being entered are unclear, and Corepharma does not address exactly what happened in their briefs. At oral argument, Corepharma argued that they heard of the Sandoz launch from customers and from filings with this Court in the Sandoz matter, but never from King. Further, it was clear that the market was not genericized on April 9

when Corepharma decided that Sandoz's actions, however brief, constituted the at-risk launch that immediately triggered their rights under the contract. The Court disagrees with Corepharma's reading of the contract, which would allow any rumors of a third party at-risk launch to serve as the mechanism that triggers their launch. King argued at oral argument that the writing requirement, though onerous and antiquated, served an important purpose in this contract: to make sure that rumors and speculations were not the basis of a Corepharma launch. It is also axiomatic to presume that a writing requirement would be imposed in the first clause of subsection ( c), which requires a 6 month waiting period, and not required in the second clause (the event of an at-risk launch), during which events and facts are likely to be intertwined with rumor and speculation. Here, there was likely no "At-Risk Launch" as defined by the contract because Sandoz was likely enjoined before marketing, distribution, or sale of any product. Further, even if there was an At-Risk launch, Core was required under the contract to wait for verification of that launch in writing: a verification that never came. Therefore, Corepharma's launch absent "verification in writing" of an at-risk launch as required by the first clause of subsection (c) of the definition of "Authorized Generic Launch Date," coupled with the likely lack of an at-risk launch that, as defined in the contract, would trigger the second clause of subsection ( c), leads the Court to presume a high likelihood of success on the merits on King's complaint.

King also argues that it gave conditional authorization to Corepharma to launch. Specifically, King notes that its CEO wrote an e-mail granting Core limited authorization to launch:

> This email constitutes written authorization to launch an Authorized

> Generic Product in accordance with the Metaxalone 800 MG Product Agreement (as amended) if you agree that under Section 3.1 (as amended) of that agreement Core will immediately cease to market and sell the Authorized Generic Product upon written notice from King if we are successful in obtaining a temporary restraining order or injunction against Sandoz.

E-mail from B. Markinson to C. Worrell. [1]

King also argues that they gave authorization to launch under subsection (d) of the Contract. Section 3.1 of the contract makes it clear that subsection (d) only applies when Core is given authorization *before* an At-Risk launch:

> [Contract provided to the Court under seal]
>
> [redacted] This is the only section of the contract that would be triggered via e-mail, as happened here. There is no way that the e-mail authorizing Core to launch could have triggered subsection (c) of the agreement. Pursuant to subsection (d), Core was required to immediately cease "*in the event and on the date that* the District Court or other decision that triggered the At Risk Launch . . . is reversed or vacated." (Contract at § 3.1.) This is the authorization that King gave to Core, and Core complied with the agreement when they ceased marketing their product after the TRO stopped Sandoz from doing the same.

[1] Though the contract contains certain clawback provisions that would could technically stop Core from launching, but none apply here.

In sum, King gave authorization via e-mail to Core to launch once Sandoz attempted an at-risk launch, which may or may not have constituted an at-risk launch pursuant to the definitions in the contract. Then, once this Court enjoined Sandoz from launching, Core properly ceased their launch as well. Thinking that subsection (c) applied to their activities, Core then re-launched absent the formal writing requirement that would trigger subsection (c). Thus, Core is in breach of the contract and King has exhibited a high likelihood of success on the merits of this action.

*2. Irreparable Harm*

"A preliminary injunction should not be granted "unless the moving party shows that it specifically and personally risks irreparable harm" *Liberty Lincoln-Mercury, Inc. v. Ford Motor Co.*, 562 F.3d 553, 557 (3d Cir. 2009). "The irreparable harm requirement is met if a plaintiff demonstrates a significant risk that he or she will experience harm that cannot adequately be compensated after the fact by money damages. . . . This is not an easy burden." *Adams v. Freedom Forge Corp.*, 204 F.3d 475, 484-85 (3d Cir. 2000).

King argues that it is being irreparably harmed by the presence of generic competition in the pharmaceutical marketplace because it will lose market share and suffer price erosion that it will never be able to regain, even if the generics are later removed from the market. (King's Br. at 16.) King argues that a sharp downward pressure will be placed on the price for their product, and the market will be permanently altered in ways that will irreversibly deprive King of its "patent-protected first-entrant advantages." (Declaration of Prof. Hausman, dated Apr. 13, 2010 ("Hausman Decl."), ¶¶ 27, 28.) Professor Hausman credibly testified that third party payors,

such as managed care plans, Health Management Organizations ("HMOs"), and Pharmacy Benefit Managers ("PBMs"), will move King's patented product off of their formularies in the presence of generic competitors, which would lead consumers to pay much more out of pocket to obtain patented Skelaxin product than to obtain the generic equivalent. (*Id.* at ¶ 28.) Professor Hausman further testified that it would be impossible to predict the future price of Skelaxin, and thus any damages later awarded to King would be imprecise. King further argues that even though King is currently facing generic competition from Sandoz, the presence of a second generic competitor (here, Corepharma) creates even more downward pressure on the price of the drug and even more confusion with regard the market for Skelaxin. (Hausman Decl. at ¶ 29.)

The Court is persuaded by King's irreparable harm arguments in this case, especially given that Core is the third entrant into the marketplace. Though King will only be harmed for a short period of time – as the contract with Corepharma provides that Corepharma shall have an unfettered right to enter the market on December 1, 2012 – the presence of two generics in the marketplace will extremely erode their market share and also make the drug subject to MAC pricing.[2] The Court also notes that two and a half years is not necessarily a "short period of time" in the pharmaceutical industry. Core has further caused harm to King by eviscerating King's standing TRO keeping Sandoz off the market, a matter which this Court is also taking under advisement.

The Third Circuit has repeatedly held that a preliminary injunction should not issue absent a showing of irreparable harm. *Liberty Lincoln-Mercury*, 562 F.3d at 557; *Adams*, 204

[2] MAC pricing, or Maximum Allowable Cost, is a formula used to calculate the maximum amount that third party payors will pay for a drug, and is only used when there are three drugs on the market.

F.3d at 484-85; *Campbell Soup Co. v. ConAgra Inc.*, 977 F.2d 86, 91 (3d Cir. 1992). "The dramatic and drastic power of injunctive force may be unleashed only against conditions generating a presently existing actual threat." *Holiday Inns of America, Inc. v. B&B Corp.*, 409 F.2d 614, 618 (3d Cir. 1969). The Court concludes that King has satisfied this necessary factor.

*3. Balancing the Equities*

"Balancing the hardships involves the question of whether, and to what extent, a defendant will suffer irreparable harm if a preliminary injunction is issued." *Kos Pharmaceuticals, Inc. v. Andrx Corp.*, 369 F.3d 700, 727 (3d Cir. 2004). King argues that it is being much more injured by Core's presence in the market than Core would be if they are kept off the market. King further argues that Core is a small company, and it is questionable whether it possesses the means to make up for the alleged damages that it is causing to King's market position. Core does not and did not respond to this argument. The Court agrees with King. Core's second launch not only harmed King by breaching the contract and causing generic competition, it also eviscerated a temporary restraining order that was keeping Sandoz on the sidelines as well. This double generic competition has harmed and is currently harming King much more than Core would be harmed by being kept off of the market for the duration of this action. The grant of this preliminary injunction will simply place core in the same position as it was in before the injunction was granted, *i.e.*, excluded from the metaxalone market. Therefore, this factor weighs heavily in favor of King.

*4. The Public Interest*

"The public interest generally weighs in favor of enforcing private contracts." *ACE*

*American Ins. Co. v. Wachovia Ins. Agency Inc.*, No. 08-4369, 2008 WL 4630486, at *9 (D.N.J. Oct. 17, 2008). Both parties argue that their actions are warranted under the contract, and that the opposing party is acting outside of its contractual rights. However, Core's position that it is acting within its rights has already been discounted by this Court. Therefore, the public interest weighs in favor of King.

## III. CONCLUSION

For the reasons stated herein, the Court will enter a preliminary injunction barring Corepharma from marketing, distribution and sale of their authorized generic form of Skelaxin. An appropriate form of order is filed herewith.

Dated: May 7, 2010

s/ Garrett E. Brown, Jr.
GARRETT E. BROWN, JR., U.S.D.J.